IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Group Art Unit 3739

In re

Patent Application of

Ronald W. Ignatius, et al.

Application No. 10/077,917

Confirmation No. 2643

Filed: February 18, 2002

Examiner: Johnson III, Henry M.

"DEVICE FOR THE TREATMENT OF MUCOSITIS"

I, Molly Seymour, hereby certify that this correspondence is being deposited with the US Postal Service as first class mail in an envelope addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

Molly Seymour
Signature

May 18, 2004
Date of Signature

DECLARATION OF TODD S. MARTIN UNDER 37 C.F.R. § 1.132

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Todd S. Martin, declare as follows:

1. I am an engineer employed by Quantum Devices, Inc. ("QDI"), which is the assignee of the above-referenced patent application (hereinafter "Present Application").

2. I have a degree in Electrical Engineering from Herzing College. I have been an engineer at QDI since 1991. I have been involved in the design and manufacture of optoelectronic devices since 1985. I am currently involved in the design and manufacture of optoelectronic devices for the treatment of mucositis.

3. I understand that, in an Office Action mailed December 31, 2003, Examiner Henry M. Johnson, III rejected Claims 1-6, 8, 9, and 15 of the Present Application under 35

U.S.C. § 102(b) as being anticipated by United States Patent No. 5,278,432 issued to Ignatius et al. (hereinafter "QDI's Prior Patent").

4. I understand that Examiner Johnson stated in the Office Action that QDI's Prior Patent discloses "a device for providing radiant energy that includes an LED array (optoelectronic device) in a housing (Fig. 5), a fan (Fig. 5, #40), and a heat sink (Fig. 5, #36) for cooling wavelengths from 620 to 680 nm and/or 700-760 nm (Col. 2, lines 5-7)."

5. I further understand that Examiner Johnson stated in the Office Action that QDI's Prior Patent discloses a "device for enhancing plant growth and irradiating other types of living cells (Col. 1, lines 63-64)."

6. Although I was aware that the device disclosed in QDI's Prior Patent could potentially be used to irradiate living cells other than plant cells, the device was specifically designed to irradiate plants for extended time periods. The device included a regulator that varied the output of the optoelectronic devices.

7. Before filing the Present Application, co-inventor Ronald W. Ignatius and I designed a new device specifically for the treatment of mucositis. Patients receiving chemotherapy often develop mucositis sores in their mouths and gastrointestinal tract due to the chemotherapy attacking the fastest growing cells in the body. Before we designed our new device, it was unknown whether the energy emitted by optoelectronic devices would even be useful for the treatment of mucositis. The effects of biostimulation of human cells using monochromatic light was not well understood. As a result, QDI's Prior Patent is devoid of any disclosure regarding a biostimulation device specifically designed to treat mucositis in humans.

8. As noted above, the device disclosed in QDI's Prior Patent was designed to irradiate plants for extended time periods. Conversely, we designed the new device that is the subject of the Present Application to treat patients very quickly in order to reduce the patient's anxiety level. We designed the new device to irradiate patients as quickly as possible (e.g., a radiation time period of about 70 seconds), while providing the appropriate light intensity (e.g.,

60 milli-Watts per centimeter squared) and the appropriate energy density (e.g., 4 Joules per centimeter squared) for the treatment of mucositis. We also designed the new device to meet safety concerns related to treating humans that were not concerns with the old device used to irradiate plants (e.g., a cover plate to electrically isolate the optoelectronic devices from the patient and a controller to provide power to the optoelectronic devices during a radiation time period suitable to treat mucositis).

9. Before we designed the new device, I was unaware of any device capable of providing such high levels of light intensity for such high levels of energy density in such a short period of time. I was unaware of any device that could produce a uniform emission of monochromatic light for the treatment of mucositis with the production of a minimal amount of heat. For example, the lasers discussed in the Background of the Present Application were unable to provide such high levels of light intensity for such high levels of energy density without subjecting the patients to intolerable heat. As a result of my being unaware of a device suitable for treating mucositis before we designed our new device, QDI's Prior Patent cannot possibly provide the disclosure necessary for one of ordinary skill in the art to make and use the new device without undue experimentation.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

5/14/04 Todd S. Martin
Date

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Molly Seymour
Signature

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Date of Signature

DECLARATION OF RONALD W. IGNATIUS UNDER 37 C.F.R. § 1.132

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ronald W. Ignatius, declare as follows:

1. I am the owner and founder of Quantum Devices, Inc. ("QDI"), which is the assignee of the above-referenced patent application (hereinafter "Present Application").

2. I have been involved in the design and manufacture of solid state light sources since 1957. I have been involved in the design and manufacture of optoelectronic light sources and sensors since 1989. I am currently involved in the design and manufacture of optoelectronic light sources for the treatment of mucositis.

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10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

5/14/04
Date

Ronald. W. Ignatius